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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/921,512	08/01/2001	Mattias Luukkonen	PRI-0019 (ORT-1461)	6102

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EXAMINER
SMITH, CAROLYN L

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 09/08/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/921,512	LUUKKONEN ET AL.	
	Examiner	Art Unit	
	Carolyn L Smith	1631	

-- The MAILING DATE of this communication appears on the c ver sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 June 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) *2-9 and 12-24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,10 and 11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-24* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4, 9* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Applicants' election with traverse of Group I (claims 1, 10, and 11) in Paper No. 14, filed 6/19/03, is acknowledged. Claims 2-9 and 12-24 are withdrawn from consideration as being drawn to non-elected Groups.

Applicants' traversal is on the grounds that Groups I-IV are related in that the methods of are all in the same classification group, and that the Examiner has not adequately demonstrated serious burden if these Groups were examined together.

The applicants' request to combine Groups I-IV into one invention was found unpersuasive because of the following reasons (summarized from the restriction paper):

Inventions in Groups I-X are related as product and the process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the gene expression profiles and microarrays of Groups V, VI, and VII may be utilized in distinct usages as needed in Group I in a method for inhibiting replication of KSHV (via c-Kit signaling pathway inhibition), in a method for inhibiting replication of KSHV (via type I sigma receptor signaling pathway) as in Group II, in a method for treatment of Kaposi sarcoma (via c-Kit signaling pathway inhibition) as in Group III, in a method for treatment of Kaposi sarcoma (via type I sigma receptor signaling pathway) as in Group IV, in a method for diagnosing KSHV or the stage of KSHV replication as in Group VIII, in a method for identifying modulators of KSHV replication as in Group IX, in a method of

doing business as in Group X, or alternatively, in gene discovery. All of these usages are distinct as requiring distinct and different functions thereof without overlapping search due to different subject matter. Examples of the different subject matter includes inhibition, treatment, and different pathways. This lack of overlapping searches documents the undue search burden if they were searched together.

The requirements are still deemed proper and are therefore made FINAL.

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The present title is directed to gene expression profile for KSHV infection and methods for treating the same, whereas in contrast the elected claims are specifically directed to a method for inhibiting replication of KSHV by inhibiting c-Kit signaling pathway.

Claims herein under examination are 1, 10, and 11.

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The declaration is defective because the filing date for provisional application 60/222,162 provided in the declaration, filed 3/19/02, is not consistent with the USPTO records. The declaration, filed 3/19/02, states the filing date of this provisional application is August 2, 2000, whereas PTO records have the filing date listed as August 1, 2000.

Claim Rejections – 35 U.S.C. 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in *Ex parte Forman*, 230 USPQ 546 (BPAI 1986) and reiterated by the Court of Appeals in *In re Wands*, 8 USPQ2d 1400 at 1404 (CAFC 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. The Board also stated that although the level of the skill in molecular biology is high, the results of experiments in genetic engineering are unpredictable. While all of these factors are considered, a sufficient amount for a *prima facie* case are discussed below.

LACK OF SCOPE OF ENABLEMENT

Claims 1 and 10 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for certain compounds to inhibit or otherwise modulate KSHV replication, does not reasonably provide enablement for all compounds. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The specification does provide enablement for using several compounds in the method that were laboratory-tested, such as 2-phenylaminopyrimidine derivate STI 571, PDTC

(pyrrolidinedithiocarbamate), trans-retinoic acid, SB203580, calcitonin gene-related peptide (CGRP), and CGRP-8-37 peptide, InCELLect AKAP St-Ht31, and St-Ht31-control peptide, haloperidol, phorbol-112-myristate-13-acetate (PMA), Ganciclovir, 15-deoxy$^{(12-14)}$ prostaglandin J2 (page 44 of specification), but does not provide reasonable enablement for the broad term "compound" as stated in claims 1 and 10. There are millions of compounds that scientists have discovered, and it would require undue experimentation to determine which compounds are effective in the claimed method. A narrower group of compounds would be required to resolve this undue experimentation issue. Also, due to the unpredictability of finding effective compounds that inhibit replication of KSHV, one skilled in the art would not be reasonably test any compound available make and use the invention in a reasonable amount of time. Therefore, the above-mentioned lack of scope of enablement rejection is set forth.

Claims Rejected Under 35 U.S.C. § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 10, and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention.

Claims 1, 10, and 11 are vague and indefinite due to the unclarity of citing an abbreviation, such as "KSHV" and "c-Kit". Correction is suggested by amending in of the full name in parentheses.

Claims 1 and 10 recite the phrase "administration of a compound" which is vague and indefinite. It is unclear what dose range is necessary to inhibit or modulate the KSHV replication, as stated in the claims. It is also unclear to what the compound is being administered. Clarification of the metes and bounds of these claims is requested. Claim 11 is also rejected due to its dependency from claim 10.

Claim 1 is vague and indefinite as it is unclear if the preamble or the step limitation controls the metes and bounds of the claim. The preamble deals with inhibiting replication of KSHV whereas the method step deals with inhibiting the c-Kit signaling pathway. Clarification of whether the preamble or the actual method step controls the metes and bounds of the claim is requested.

Claim 10 is rejected due to the unclarity of the phrases "administration of a compound that inhibits c-Kit" and "administration of a compound that modulates KSHV replication by a mechanism other than inhibition of c-Kit". One interpretation is that there are two compounds involved in this administration method. Another interpretation is that there is only one compound used in the method based on the concept that it is well known that compounds may well have two or modes of action, as commonly seen in a prescription medicinal compound that treats a particular mechanism and also contains side effects due to its involvement in other pathway mechanisms. Claim 11 is also rejected due to its direct dependency from claim 10.

Claim 11 is rejected due to the unclarity as to whether the compounds listed (daunorubicin, doxorubicin, interferon alpha, retinoids, and taxol) accomplish both of the activities stated in claim 10, including c-Kit inhibition and another form of modulation of KSHV replication.

Claim Rejections – 35 USC §102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 10, and 11 are rejected under 35 U.S.C. 102(e)(2) as being anticipated by Capon et al. (P/N 6,103,521).

One reasonably broad interpretation of claim 1 is that there is no direct inhibition required of the c-Kit signaling pathway. Capon et al. disclose using multispecific chimeric receptors containing multispecific extracellular inducer-responsive clustering domain to recognize antigens or epitopes from a single pathogen to treat Kaposi's sarcoma-associated herpes virus (KSHV) (col. 16, lines 58-67). Capon et al. disclose using proliferation signaling domains from tyrosine kinase growth factor receptors, including c-Kit. Although the site of action is not defined in the treatment stated by Capon et al., one reasonable interpretation of treatment to a viral infection is that it would essentially stop all viral activities, including its replication, as stated in claim 1. Capon et al. disclose administering a dose of taxol to a patient (col. 17, lines 57-65). Due to the unclarity of instant claims 10 and 11, which can be interpreted to mean one compound is administered for the two effects (instant claim 10) and the compound taxol stated to meet these requirements (instant claim 11), Capon et al. anticipate the method of administering taxol. Capon et al. disclose the application of combination therapies for treatments

of herpes virus infections although side-effects may occur (col. 1, lines 58-64). Thus, Capon et al. anticipate the limitations of claims 1, 10, and 11.

Conclusion

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR §1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Smith, whose telephone number is (703) 308-6043. The examiner can normally be reached Monday through Friday from 8 A.M. to 4:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner Tina Plunkett whose telephone number is (703) 305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

September 3, 2003

ARDIN H. MARSCHEL
PRIMARY EXAMINER